REMARKS

The applicants have studied the Office Action dated April 2, 2003, and have made amendments to the claims. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claim 35 has been cancelled without prejudice or disclaimer, and claims 1, 18, 34, and 36 have been amended; thus, claims 1-4, 7-19, 21-24, 34, and 36 are pending. Consideration and allowance of all the pending claims in view of the above amendments and the following remarks are respectfully requested.

Claims 1-4, 7-19, 21-24, and 34-36 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-24, and 34-36 of copending Application No. 09/940,369. The applicants also note with appreciation that claims 19 and 21-24 have been indicated as being allowable if rewritten to overcome this provisional obviousnessness-type double patenting rejection.

In an Amendment dated August 25, 2003 in connection with copending Application No. 09/940,369, the applicants cancelled claims 20-24, 35, 38, and 58, and amended claims 1-5, 7-19, and 34-36 to include language recited in former claims 38 and 58 of that application, which were not provisionally rejected under the doctrine of obviousness-type double patenting. Thus, it is respectfully submitted that the provisional rejection of claims 1-4, 7-19, 21-24, and 34-36 of the present application under the judicially created doctrine of obviousness-type double patenting should now be withdrawn. Further, it is respectfully submitted that claims 19 and 21-24 are now in condition for allowance.

Claim 4 and 17 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Claims 4 and 17 recite that the second member is made of stainless steel. The Examiner indicated that the specification disclosed the second member being made of metal, but not specifically stainless steel. However, the applicants respectfully point out that page 19, lines 19-23 of the specification discloses that the second member (i.e.,

insert) may be made of "hard plastic, stainless steel or other preferably relatively stiff material." Therefore, withdrawal of the rejection of claims 4 and 17 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claim 36 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner indicated that claim 36 depended from itself. In response, the applicants have amended claim 36 to depend from claim 34. Thus, withdrawal of the rejection of claim 36 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 1-4, 7-18, and 34-36 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kakimi et al. This rejection is respectfully traversed.

Embodiments of the present invention are directed to an apparatus for dispensing a medication fluid, which includes a reservoir and a piston. The reservoir is adapted to contain the fluid and is adapted for use with a drive system having a linear actuation member. Referring to Figs. 14-17, the piston includes a first member 1404 having an external proximate side 1501 and an external distal side 1505. The first member 1404 is adapted to be slidably mounted within the reservoir 406 and to form a fluid-tight barrier within the reservoir 406. The external proximate side 1501 of the first member 1404 is adapted to contact the fluid and is made of a material having a first stiffness. The external distal side 1505 of the first member 1404 is adapted to releasably engage the linear actuation member. Referring to Figs. 15c and 17, a second member 1201 is not required to couple the first member 1404 to the linear actuation member; instead, the first member 1404 itself is adapted to engage the linear actuation member. The piston also includes a second member 1201 having a first side 1601 and a second side 1602. The first side 1601 and the second side 1602 of the second member 1201 are entirely contained within the first member 1404, and the second member 1201 is adapted not to contact the fluid. Referring to Figs. 15c and 17, no portion of the second member 1201 extends beyond the external proximate side 1501 or external distal side 1505 of the first member 1404. In the illustrated embodiments, the second member 1201 is removable from the first member 1404. However, in other embodiments, the first member 1404 may be constructed with no openings or cavities, and the

second member 1201 may be encased within the first member 1404 such that the second member 1201 is not removable from the first member 1404 (see Specification, page 22, lines 2-6). Further, the first side 1601 of the second member 1201 is adjacent to the external proximate side 1501 of the first member 1404, and is made of a material having a stiffness that is greater than the first stiffness. As a result, the second member provides stiffness to the first member, and reduces undesirable deformation of the piston.

Claim 1, and claims 2-4 and 7-17 depending therefrom, recite an apparatus for dispensing a medication fluid comprising a reservoir adapted for use with a drive system having a linear actuation member, and a piston including a "first member having an external proximate side and an external distal side, the external proximate side being adapted to contact the fluid and being made of a material having a first stiffness, the external distal side being adapted to releasably engage the linear actuation member"; and "a second member having a first side and a second side, the first side and the second side of the second member being entirely contained within the first member and being adapted not to contact the fluid" (emphasis added). Claim 34, and claim 36 depending therefrom, recite similar language. The Kakimi et al. reference fails to disclose, teach, or suggest a piston including a first member with an external distal side that is adapted to releasably engage a linear actuation member, and a second member with first and second sides that are entirely contained within the first member, as recited in the claims.

The Kakimi et al. reference is directed to a medical syringe. Referring to Figs. 1 and 2, the syringe 2 includes a syringe body 3 and a plunger 4 fitted in the syringe body 3. The plunger 4 comprises an elastic cover 9 (first member) and a plunger body 5 (second member), and the elastic cover 9 is fitted over the plunger body 5 from the front. However, the distal side of the elastic cover 9 (first member) is not adapted to releasably engage a linear actuation member, such as piston 13. Instead, the distal side of the elastic cover 9 (first member) is coupled to the plunger body 5 (second member), which in turn releasably engages the piston 13. Independent claims 1 and 34, and the claims depending therefrom, have been amended to further clarify that the first member itself engages the linear actuation member, rather than being coupled to the linear actuation member through the second member. Thus, the Kakimi et al. reference does not

disclose, teach, or suggest a piston including a first member with an external distal side that is adapted to releasably engage a linear actuation member, as recited in claims 1-4, 7-17, 34, and 36.

Additionally, the first and second sides of the plunger body 5 (second member) are not entirely contained with the elastic cover 9 (first member), as in the claimed embodiments. The plunger body 5 includes three components 6, 7, and 8 that are fitted to one another in an axial arrangement. As shown in Fig. 2, when the plunger body 5 is fitted together, the plunger body 5 has its first side at the tip of the third component 8, and its second side at the backplate 62 of the first component 6. The first and second components 6 and 7 of the plunger body 5 (second member), and thus, the first and second sides of the plunger body 5 (second member), are not entirely contained within the elastic cover 9 (first member). Independent claims 1 and 34, and the claims depending therefrom, have been amended to further clarify that both the first and second sides of the second member are contained within the first member, and thus, no portion of the second member extends beyond either the external distal side or external proximal side of the first member. Therefore, the Kakimi et al. reference also does not disclose, teach, or suggest a piston including a second member with first and second sides that are entirely contained within the first member, as recited in claims 1-4, 7-17, 34, and 36.

Claim 18 recites an apparatus for dispensing a medication fluid comprising a reservoir adapted for use with a drive system having a threaded linear actuation member, and a piston including a first member having a cavity that includes a first chamber, which "is defined by a generally cylindrically-shaped first wall extending axially from the external distal side into the cavity, and the generally cylindrically shaped first wall has threads adapted to releasably engage the threaded linear actuation member" (emphasis added). The Kakimi et al. reference fails to disclose, teach, or suggest a piston including a first member having a cavity with a first chamber that is defined by a wall with threads adapted to releasably engage a threaded linear actuation member, as recited in the claim.

As discussed above, in the Kakimi et al. reference, the elastic cover 9 (first member) is not adapted to releasably engage a linear actuation member, such as piston 13. Instead, the distal side of the elastic cover 9 (first member) is coupled to the plunger body 5 (second member), which in turn releasably engages the piston 13. Further, the elastic cover 9 (first member) does not include threads adapted to releasably engage a threaded piston, as in the claimed embodiment. Thus, the Kakimi et al. reference fails to disclose, teach, or suggest a piston including a first member having a cavity with a first chamber that is defined by a wall with threads adapted to releasably engage a threaded linear actuation member, as recited in claim 18.

For these reasons, withdrawal of the rejection of claims 1-4, 7-18, and 34-36 under 35 U.S.C. § 102(e) is respectfully requested.

Claims 1-4 and 7-10 were rejected under 35 U.S.C. § 102(b) as being anticipated by Namey, Jr. This rejection is respectfully traversed.

Claim 1, and claims 2-4 and 7-10 depending therefrom, recite "the first member having an external proximate side and an external distal side, the external proximate side being adapted to contact the fluid and being made of a material having a first stiffness, the external distal side being adapted to releasably engage the linear actuation member" and "a second member having a first side and a second side, the first side and the second side of the second member being entirely contained within the first member and being adapted not to contact the fluid" (emphasis added). The Namey, Jr. reference fails to disclose, teach, or suggest a piston including a first member with an external distal side that is adapted to releasably engage a linear actuation member, and a second member with first and second sides that are entirely contained within the first member, as recited in the claims.

The Namey, Jr. reference discloses a plunger used in a syringe. Referring to Figs. 2 and 3, the plunger 20 includes a rubber exterior 32 (first member) overmolded onto a hard plastic core 30 (second member). However, the distal side of the rubber exterior 32 (first member) is not adapted to releasably engage a linear actuation member, such as the plunger drive ram.

Instead, the distal side of the rubber exterior 32 (first member) is coupled to the plastic core (second member), and a button 26 extends from the plastic core 30 (second member) to engage the plunger drive ram (col. 3, lines 2-7). Independent claim 1 and the claims depending therefrom have been amended to further clarify that the first member itself engages the linear actuation member, rather than being coupled to the linear actuation member through the second member. Thus, the Namey, Jr. reference does not disclose, teach, or suggest a piston including a first member with an external distal side that is adapted to releasably engage a linear actuation member, as recited in claims 1-4 and 7-10.

Further, the first and second sides of the plastic core 30 (second member) are not entirely contained within the rubber exterior 32 (first member). Instead, the rubber exterior 32 (first member) only envelops the distal end 22 (first side) of the plastic core 30 (second member), and the proximal end 24 (second side) of the plastic core 30 (second member) extends beyond the distal side of the rubber exterior 32 (first member) (col. 3, lines 9-20). Independent claim 1 and the claims depending therefrom have been amended to further clarify that both the first and second sides of the second member are contained within the first member, and thus, no portion of the second member extends beyond either the external distal side or external proximal side of the first member. Therefore, the Namey, Jr. reference does not disclose, teach, or suggest a piston including a second member with first and second sides that are entirely contained within the first member, as recited in claims 1-4 and 7-10.

Accordingly, withdrawal of the rejection of claims 1-4 and 7-10 under 35 U.S.C. § 102(b) is respectfully requested.

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If, for any reason, the Examiner finds that the application is other than in condition for allowance and believes that a telephone interview would advance the prosecution of the application, the Examiner is invited to call the undersigned attorney at (818) 576-5291.

Respectfully submitted,

Date: September 2, 2003

By: _____
Vivian S. Shin
Reg. No. 43,919

MEDTRONIC MINIMED, INC.
18000 Devonshire Street
Northridge, CA 91325
Telephone: (818) 576-5291
Facsimile: (818) 576-6202